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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,032	09/24/2003	David C. Racenet	1879 CON II	5015
Covidien 60 Middletown Avenue North Haven, CT 06473			EXAMINER NGUYEN, CAMTU TRAN	
			ART UNIT 3772	PAPER NUMBER
			MAIL DATE 02/10/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/670,032		RACENET ET AL.	
	Examiner		Art Unit	
	Camtu T. Nguyen		3772	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-10, 22, 24-26 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) 6, 8 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 7, 9, 10, 22, 24-26, 28-30, 32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/22/08 & 9/25/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This Office Action is responding to applicant's amendment filed on 2-27-2008. Claims 5, 7, 24, and 26 have been amended. Claim 27 has been cancelled. Claims 32 & 33 are newly added.

Applicant's comments directed toward the prior arts applied in the previous Office Action are noted, thus, those prior arts have been removed.

Applicant stated that a Terminal Disclaimer will be filed upon indication of allowability of the claims. As such and until a Terminal Disclaimer is filed, the nonstatutory obviousness-type double patenting is maintained.

The claims, as amended, have been carefully considered and are rejected as follows, based on new grounds of rejection, which was necessitated by applicant's amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 7, 9, 10, 22, 24-26, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mollenauer et al (U.S. Patent No. 5,634,937) in view of Stablein (DE 37 37 121 A1).

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Mollenauer et al discloses a trocar stabilizer device (10) for accessing to body tissue, the device (10) comprising an access member (22) having a longitudinal passage for purposes of receiving an endoscope (34), a seal (20) disposed within the access member (22) and having an aperture therethrough, as shown in Figure 5, the seal (20) expands from a relaxed state (Figure 5) to a stressed state upon passage of the endoscope (34) in a seal relation therewith (Figures 8 & 17).

Figure 5 illustrates the seal (20) having a tapered portion of a conical configuration.

Mollenauer et al discloses the seal (20) is of elastic biocompatible material (column 6 lines 42-49), of which is resilient.

With regards to claim 5 & 24 reciting "adapted", it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires to ability to so perform. It does not constitute a limitation in a patentable sense. In re Hutchison, 69 USPQ 138.

The Mollenauer et al device does not disclose the seal comprising a fabric material as recited in claims 5, 24, 26, and 29.

Stablein further discloses a sealing system for catheter/instrument insertion assembly, the sealing sleeve (2) is made of soft and flexible but tear-resistant material (natural or synthetic or soft plastic) and a fabric material is used to reinforce sealing sleeve (2), see last paragraph of column 2.

Therefore, it would have been obvious to one skilled in the art to modify the material of the Mollenauer et al seal (20) such that it would include a layer of fabric, as taught by Stablein,

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as such would provide not only flexibility during insertion of the endoscope (34) but also greater resistance, thus, to form a tighter fluidic seal in relation about the endoscope (34).

With regards to claim 30 reciting the fabric disposed on each of opposed surfaces of the resilient seal, it would have been obvious to one having ordinary skill in the art at the time the invention was made situate the fabric on each of opposed surfaces of the resilient seal, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Claims 5, 24, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stephens et al (U.S. Patent No. 5,350,364) and further in view of Stablein (DE 37 37 121 A1).

Stephens et al discloses a trocar assembly (10) to provide access for surgical instrument during endoscopic surgical procedure comprising all of the element as recited in applicant's claims including the seal (234) is non inflatable (claims 32 & 33), the seal (234) is of resilient material such as silicone (column 8 lines 65-67) but the seal (234) does not comprising a fabric material as recited in independent claims 5 and 24.

Stablein further discloses a sealing system for catheter/instrument insertion assembly, the sealing sleeve (2) is made of soft and flexible but tear-resistant material (natural or synthetic or soft plastic) and a fabric material is used to reinforce sealing sleeve (2), see last paragraph of column 2.

Therefore, it would have been obvious to one skilled in the art to modify the material of the Stephens et al seal (234) such that it would reinforced by fabric, as taught by Stablein, as

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such would minimize frictional forces while inserting/moving implements inside the trocar device (10).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5 and 24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,545,179 to Williamson, IV in view of U.S. Patent No. 7,244,244 to Racenet et al. Williamson, IV discloses an access assembly to provide access for surgical instrument during endoscopic surgical procedure comprising all of the element as recited in applicant's claims but does not disclose the tapering sealing (26) comprising a fabric material and being disposed within the access member, as recited in independent claims 5 and 24. Racenet et al discloses in claims 1, 2, 4, 5, 8-10, 14, 20, 22, 23, 24 a layer of fabric attached to the seal member. Therefore it would have been obvious to

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one skilled in the art during the time of the invention to modify claim 1 of U.S. Patent No. 5,545,179 (Williamson, IV) to provide a layer of fabric as taught by Patent No. 7,244,244 (Racenet et al) for the purposes of providing greater resistance, thus, to form a tighter fluidic seal in relation about the elongated object.

Claims 5, 7, 9, 10, 22, and 24-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-13 and 16-19 of copending Application No. 10/718,195 (according to PAIR system, the latest amendment is Examiner's Amendment mailed out on June 6, 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in co-pending application #10/718,195 reciting the seal member having an hourglass configuration anticipates the seal member having a general conical configuration in this instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772